

sufficiently large as to be more recognizable as legs and feet and may be permanently attached to the case, formed as a unitary piece when the outer case is bent into shape, or may be attached to the case in a permanent or removable manner. When the legs and feet are attached separately to the outer case (by either permanent or removable means), they may be constructed of any suitable materials that are compatible with the sterilization method for which they are intended. They are not required to be of the same materials as the outer case, lid and/or inner tray, but preferably they are constructed from a material selected from the same group of materials that are suitable for the outer case. Most preferably, such legs and feet are made of the same material as the outer case.

[0025] As previously stated, the perforations (8)(9) present in the outer case (1) surfaces, the outer case lid (4) surfaces, and the inner tray (3) surfaces may be in any desired pattern or placed randomly. Most preferably, the pattern and sizing of the perforations (9) in the inner tray (3) are such that when the inner tray (3) is placed on the liner (2) and in the outer case (1), the perforations (9) in the inner tray (3) are offset from the perforations (8) in the outer case (1) so as to prevent any sharp portions of the instruments or devices being sterilized from being able to strike through from the inner tray (3) through the liner (2) and through the outer case (1). Any sharp points which might penetrate the perforations (9) of the inner tray would then be prevented from piercing the liner (2) as it would strike a solid surface of the outer case (1). The offset of the perforations also aids in creating a tortuous path for the sterilant to follow and thereby aid in dispersing the sterilant to all surfaces of the object being sterilized. The inner tray (3) may also have an engageable inner tray lid (10) that is similar to the lid for the outer case (1), except that it is sized for the inner tray (3). While the inner tray lid (10) is not absolutely required, it does provide a flat surface for use in the folding of the liner (2) when wrapping the inner tray (3). The inner tray lid (10) is particularly useful if one wishes to place the objects to be sterilized into the inner tray (3), wrap the inner tray (3) with the liner (2) and then place the wrapped inner tray into the outer case (1), as the inner tray lid (10) provides a rigid top surface against which the liner (2) can be pressed during the wrapping operation, secured by tape or a fastener without breaking the liner (2), and provides firm surfaces for transport of the wrapped inner tray to the outer case (1).

[0026] The liner (2), which is placed between the outer case (1) interior surface and the inner tray (3) outer surface, serves to wrap the inner tray (3) and the objects to be sterilized that are contained therein. The liner also advantageously serves as a microbial filter so that the once sterilized, the wrapped inner tray will remain sterile until use. The liner (2) material is thus selected from the group consisting of disposable or reusable materials such as medical grade cellulosic materials (for example paper, etc.); polypropylene or other non-woven polyolefins; linen or muslin, etc; or synthetic wrap (for example Gortex, Teflon, polyfoil compounds, tyvek, etc.); or mixtures or blends. In addition, the liner (2) may be a composite of multiple layers where each layer provides some, but not all of the desired characteristics; however, since multiple layer liners become increasingly difficult to properly fold, their use is less advantageous, but still within the scope of the present invention. The liner (2) material may be configured in flat sheets (as shown in FIG. 4), in peel pouches, or bags.

Especially useful are bags and pouches with self closures contained therein. Flat sheets are also a preferred configuration as it allows for use of one size sheet for multiple sizes of inner trays (3) to be wrapped. Furthermore, as the outer case (1) provides a secondary protective surface for the contents, the liner (2) itself may be a single wrap as opposed to double wrapping or sequential layering of multiple wrap layers.

[0027] The liner (2) may be folded around the inner tray to enclose it (and the objects to be sterilized) in any manner conveniently known in the art. Two such methods are shown for double wrapping in FIGS. 1 and 2. Single wrapping in the same manner is perfectly suitable for the present invention. Still other wrapping methods will be apparent to those of ordinary skill in the art. Once wrapped, the folded liner (2) is fastened with any suitable fastening manner, such as adhesive, tape, clips, clamps, etc. In the case of a reusable liner (2) material, a particularly suitable fastening mechanism is the use of Velcro, which would be suitably attached to the liner (2) material when the liners (2) are made. Where the liner (2) material is configured as a bag or pouch, self closures as typically seen in plastic sandwich and freezer bags are also suitable.

[0028] The outer case (1) and/or the outer case lid (4) may be equipped with one or more latching means (not shown) to secure the outer case (1) and the outer case lid (4) together. Optional clips or holders located externally to the outer case (1) and/or outer case lid (4) may be present for attachment of a tamper-proof seal, and are preferably employed. Any tamper-proof or tamper-resistant sealing mechanism known in the art that is compatible with the sterilization procedure is suitable for use in the present invention, and those of ordinary skill will be well aware of such methods.

[0029] The inner surfaces of the outer case (1) and the outer surfaces of the inner tray (3) are preferably smooth, and free from rough edges at the perforation (8)(9) hole edges so as to minimize snagging of the liner (2) (and potentially causing a tear in the liner (2)) in the process of placing the liner (2) and inner tray (3) into the outer case (1). The inner tray (3) protects the liner (2) from potential tears from the object being sterilized, while the outer case (1) protects the liner (2) from potential tears and compromised sterility maintenance from the point the inner tray (3) is placed inside the outer case (1), through the sterilization procedure, through storage, until use.

[0030] The outer case is preferably equipped with one or more handles (not shown) for ease of handling the assembled sterilization unit. These handles may be in a fixed position which does not interfere with stacking of various units, or may be in any position if they are movable and can be moved to a position that allows for stacking of individual units. Such handles are well known in the art. Handles may be made of any suitable material and may, but need not, be made from the same materials as the rest of the outer case. Handles may be permanently affixed to the outer case (1) or may be removable by engagement and disengagement of handle attaching means (not shown in the figures) located at any suitable position of the outer case (1).

[0031] In an alternative embodiment (see FIG. 5), the outer case (1) is a hinged device having a bottom (51) and four side walls (52) where the hinged side walls are hinged